

REMARKS

This Amendment is in response to the Office Action dated November 29, 2007 in which Claims 1-9, 17 and 18 were rejected and Claims 10-16 were withdrawn from consideration.

In reviewing the claims again, Applicants note that the claims of Group I should include Claims 1-10 and 16-18. Claim 10 is dependent upon Claim 8, which is dependent upon Claim 1. Thus it is included in claims to a method of suppressing or eliminating tumor cells. Claim 16 also depends from Claim 1 and should be included in Group I. Applicants respectfully request that the Examiner include Claims 10 and 16 in the Group I election.

Claims 1, 2, and 18 have been amended. Support for the amendments is found in the originally filed claims.

Objection of the Specification

The specification is amended to capitalize the trademarks. Applicants believe that all trademarks are now correctly identified.

Rejection of Claims 1-9, 17 and 18 Under 35 U.S.C. § 112, First Paragraph

Claims 1-9, 17 and 18 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable treatment for other tumor types other than mammary carcinoma. Applicants respectfully disagree with the Examiner.

The basis of the Examiner's argument is that one skilled in the art would not believe that a single agent could treat all tumor types. However, the combination of whole glucan particles with an antitumor antibody is not a single agent as that term is used in the Cecil reference. The term "antitumor antibody" reflects a general category of antibodies, even though there is a specific antibody used for each type of tumor. Whole glucan particles work synergistically with each antitumor antibody for the particular tumor targeted. Thus, the Cecil reference is not dispositive with regard to Applicants' invention.

In addition, one of skill in this particular art would expect to perform more experimentation than in many other fields and would not consider it undue experimentation. The Specification sets forth certain characteristics, such as complement activation, that the antibody must possess for it to be useful in the present invention. This is possible because the inventors

have determined the basic mechanism of action for this combination as set forth in the claims. Thus, the Specification provides a general description of the type of antibody that works in the present invention, which in turn provides a reasonable expectation of success. The number of candidate antibodies is described by the terms of the Specification (See page 19, line 24 to page 23, line 19) and thus do not include all antibodies but a narrowed class. Thus, the claims are a described class of antibodies and can be tested with simple and routine *in vitro* tests. Therefore, there is no need for extensive, undue experimentation.

This type of information would also guide a skilled artisan to develop the type of antibodies needed for use with the present invention. Given the potential results if successful, the skilled artisan may not even consider antibody development to be undue. In light of the above discussion, the combination of whole glucan particles and an antitumor antibody are not a single agent for all tumor types and would not require undue experimentation for treatment of various tumor types.

Claim 2 was rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicants have amended the claim thus rendering the rejection moot.

Claim 4 was rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner states that the specification does not provide sufficient guidance to predict a “synergistic antitumor effect.” Applicants respectfully disagree.

Applicants believe the Examiner is underestimating the considerable experimentation that is performed in this field. The skilled artisan would expect to perform preliminary testing, which can, again, be simple *in vitro* tests to determine the synergistic effect of the combination. This type of testing would be routine and may be performed with each different antitumor antibody used in the combination therapy. Such experimentation would not be considered undue. In light of the discussions above, reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1-9, 17 and 18 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-9, 17 and 18 were rejected under 35 U.S.C. §112, second paragraph, because the language “effective amount” is vague and indefinite. Applicants have amended Claims 1 and 18 such that the rejection is moot.

Rejection of Claim 1-9 Under 35 U.S.C. §103(a)

Claims 1-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over James *et al* (U.S. Patent No. 5,532,223), in view of Leyland-Jones (The Lancet, Oncology Vol. 3, March 2002). Applicants respectfully disagree.

Neither reference indicates that whole glucan particles act synergistically with antitumor antibodies to treat tumors as is recited in Applicants' claims. At best, the expectation would be that each component acts through separate mechanisms possibly resulting in an additive effect.

Rejection Under the Judicially Created Doctrine of Obviousness-type Double Patenting

Claims 1-7, 15-16, 18-20 and 22-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Application No. 10/526,185. Applicants respectfully submit that these applications are patentably distinct as each is directed to the use of a different composition. The present application is directed to insoluble whole glucan particles and the claims of U.S. Application No. 10/526,185 are directed to a neutral soluble glucan. In view of these differences, Applicants respectfully request reconsideration and withdrawal of the rejection.

Information Disclosure Statement

A Supplemental Information Disclosure Statement (SIDS) is being filed concurrently herewith. Entry of the SIDS is respectfully requested.

CONCLUSION

In summary, it is concluded that the art cited by the Examiner does not render Applicants' claimed invention obvious. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call Alice O. Carroll, Esq. or the undersigned at (978) 341-0036.

Respectfully submitted,

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